JUL - 3 2001

K011032

510(k) Summary for the SmartJet Bone Grafting Liquid Applicator (Revised 6/29/01)

Submitter's Name and Address:	Harvest Technologies Corp. 40 Grissom Road, Suite 100
Phone Number:	508-732-7530
Telefax Number:	508-732-0400
Contact Person:	Annette M. Fagnant, Director, Regulatory Affairs
Date Summary Prepared:	April 2, 2001
Device Trade Name:	SmartJet Bone Grafting Liquid Applicator
Classification Name:	Piston Syringe
Predicate Devices:	The SmartJet Bone Grafting Liquid Applicator is substantially equivalent to other bone grafting liquid dispensers previously cleared by the FDA via the 510(k) process (e.g., DePuy Acromed Symphony Graft Delivery Syringe)
Device Description:	The SmartJet Applicator will be configured using the following components: • Two commercially available disposable medical piston syringes, • Applicator tip (spray or dual cannula) • Handle frame, and • Plunger clip.
Intended Use:	Designed to facilitate pre-mixing of allograft, autograft, or synthetic bone graft materials for application to an orthopedic surgical site, with I.V. fluids, autologous blood, plasma, platelet rich plasma, or other specific blood component(s) as deemed necessary by the clinical use requirements.
Technological Characteristics/ Performance Data:	The proposed device has the same technological characteristics and is similar in design and configurations compared with the predicate device. The materials of manufacture have been demonstrated to be suitable for the intended use specified.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 3 2001

Ms. Annette Fagnant
Director, Regulatory Affairs
Harvest Technologies Corporation
40 Grissom Road, Suite 100
Plymouth, Massachusetts 02360

Re: K011032
Trade/Device Name: SmartJet Bone Grafting Liquid Applicator (LYC)
Regulatory Class: Unclassified
Product Code: LYC
Dated: April 4, 2001
Received: April 5, 2001

Dear Ms. Fagnant:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement
(Revised June 29, 2001)

510(k) Number (if known): K011032

Device Name: SmartJet Bone Grafting Liquid Applicator

Indications for Use: The SmartJet Bone Grafting Liquid Applicator is designed to facilitate pre-mixing of allograft, autograft, or synthetic bone graft materials for application to an orthopedic surgical site, with I.V. fluids, autologous blood, plasma, platelet rich plasma, or other specific blood component(s) as deemed necessary by the clinical use requirements.

(Please do not write below this line-continue on another page if needed)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-The-Counter Use**_____
(Per 21 CFR 801.109)

for Mark N Melkerson
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K011032